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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,714	06/23/2003	Win L. Chiou	14123.2US11	6913
23552	7590	07/06/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,714	Applicant(s) CHIOU ET AL.	
	Examiner Gina C. Yu	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/03, 8/5/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Applicants' disclosure fails to enable the full scope of the claimed methods of claim 36. The claimed method "for prophylaxis and treatment of facial acne" was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Evaluation of enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

a) The breadth/nature of the claims: The invention requires a method step of topically administering to the facial skin surface of a human an aqueous composition,

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consisting essentially of an effective amount of one or more nonvolatile, slowly absorbed, water miscible liquid organic substances, and water, wherein the liquid organic substance is present from about 4-99.9% by weight, wherein the liquid organic substance is slowly absorbed into the facial skin over a period of time for at least about 4 hours. The scope of the said liquid organic substances is broad, as the limitation recites the physical properties of such substances rather than the specific compounds.

b) the state of the prior art: the state of the prior art uses applicants' organic solvents as a topical vehicle rather than an active anti-acne component. For examples, US 5914334 discloses a gel composition comprising polyethylene glycol-400 and synthetic retinoid for treating acne.

c) the level of predictability in the art: The predictability of the efficacy of the present invention is low because applicants are essentially claim that the nonvolatile, slow-absorbing water-miscible organic liquid alone will act as the anti-acne agents. The examples of the polyols which applicants disclose in the specification have been used on skin as humectants that provide moisture retention, elasticity, flexibility, softness, and protection to the skin, and yet examiner is not aware of any report that these polyols alone will prevent or treat acne. See US 5977188.

d) the amount of direction and working example provided by the inventor: There is no direction or working examples in the specification for a skilled artisan to know how to make/use the claimed invention. The specification simply indicates that a composition "similar to Example V containing about 55 % by weight of glycerin" and an aqueous solution of polyethylene glycol 400, each containing a large quantity of saliva

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samples, developed no microorganism growth when exposed to ordinary room air over a 3 –month period. This disclosure does not provide adequate direction for a skilled artisan to use the claimed method of treating microorganisms on the skin or preventing/treating acne because there is no reasonable link between the acne-causing bacteria, and the microorganism in saliva. Examiner is not aware of and unable to find any scientific evidence that would prove the alleged correlation between the microorganisms from human saliva and acne. Rather, it is well known in the art that specific bacterial strands in skin and hair follicle cell cause acne. See US 6150381, col. 1, line 34 – col. 2, line 16.

Furthermore, the claimed invention is directed to using a composition comprising essentially of as low as 4 % of the liquid organic substance in water, while applicants disclosure only shows examples containing 53% and 55 % of polyethylene glycol 400 and glycerine, respectively. Thus, the disclosure does not support the scope of the claimed invention.

e) the quantity of experimentation needed to make or use the invention based on the content of the disclosure:

Since applicants disclose no adequate working example, guidance, or reasonable basis for a skilled artisan to believe that the claimed method of preventing and treating acne will work as explained above, numerous experimentations will be needed to make or use the invention as claimed. Furthermore, the present claim is directed to the method of preventing a certain skin condition, which requires monitoring the protocol of the human subjects over protracted period of time.

For the reasons above, undue experimentations will be needed to test the efficacy of the claimed invention, as there is no sufficient disclosure to enable the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, 15, 22, and 29 are vague and indefinite as the metes and bounds of the scope of the claim are not clear. What is "an aqueous composition that is not a water-miscible cream, ointment or lotion"? Is the invention limited to a solution, paste, gel, or dispersion of any specific rheology, and if so, what is the standard to determine (e.g., viscosity) whether a composition meets the limitation of not being a "cream", "ointment" or "lotion"? Furthermore, it is not clear whether an oil-in-water cream or lotion meets the claimed limitation because such emulsion is considered an aqueous composition but its dispersion or oil droplets are not water-miscible. The claim is deemed vague and indefinite as it fails to clearly define what is included in the claim limitation.

In claim 36, the phrase, "treating microorganism" renders the claim vague and indefinite. Do applicants mean treating an *infection* by microorganism or *eliminating* microorganism?

The remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-10, 12, 14-17, 19, 21-24, 26, 28-31, 33, 35-38, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Okamoto et al. (US 5977188) (“Okamoto”).

Okamoto discloses a method of treating facial skin by applying a toilet water comprising 5% of 2-methyl-1, 3-propanediol (glycol) and 5% of glycerine as active ingredients. See Example 11. See instant claims 1, 3, 5, 8, 10, 12, 15, 17, 19, 29, 31, 33, 34. According to Table 2, a panel found that the composition improves the skin and treats facial wrinkle. See also Example 13, an emulsion comprising 7 % of 2-methyl 1,3-propane diol and 5 % of glycerine as the active ingredients and 0.5 % of sodium pyrrolidonecarboxylate (viscosity modifier). See instant claims 7, 17, 21, 28, and 35. The reference also teaches that treating dry skin by providing moisture results in elasticity, flexibility, and protective functions of the skin. See col. 1, lines 19 – 33,

A normal skin corneum (stratum corneum) usually contains 10-20 % of moisture and retains elasticity, flexibility and protective functions. However, when the moisture of the corneum decreases due to changes in the external environment factors such as the temperature and humidity, a condition called dry skin occurs and the skin loses elasticity and protective functions, leading to various troubles.

Conventionally, hydrophilic humectants have been blended into cosmetics for the purpose of improving or preventing such dry skin.

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The hydrophilic humectants used for this purpose include the polyol type humectants such as dipropylene glycol, polyglycerine, 1,3-butylene glycol, glycerine, and polyethylene glycol.

Thus the method of treating the skin with the prior art composition by providing moisture to skin inherently increases the elasticity and firmness of the skin. See instant claims 22 and 29.

While the absorption time of the glycols as recited in the present claims 2, 9, 16, 23, and 30 are not taught in the reference, since the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). It is also well settled in patent law that, when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. See In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, the absorption time as claimed is viewed an inherent property of the composition comprising the polyols since the applicants' compositions read on the prior art compositions comprising the same glycols. See also the properties of 2-methyl-1,3-propanediol in col. 2, lines 3 – 44.

Although Okamoto does not specifically teach the claimed method of “treating microorganism on facial skin surface”, the reference discloses the method of applying to facial skin an oil-in-water cream composition comprising 1% polyethylene glycol, 5 % 1,4-butane diol, 5 % 2-methyl-1,3-propane diol, and 5 % glycerine; and Vaseline and xanthan gum (gelling agents). See also comparative example 2; see instant claims 36,

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38, 40, and 42. It is well settled in patent law that the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See In re Best, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430, 433 (CCPA 1977). Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. See In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). Since the Okamoto composition meets all the limitation of the composition used in the present invention, and the administration of the prior art composition to the facial skin as disclosed would necessarily result in the treatment of microorganism on the skin, the prior art method inherently performs the method of claim 36.

It is also noted that the claims require that the compositions consist essentially of water and the organic solvent(s), whereas the prior art compositions comprise cosmetic additives such as oil and surfactant. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See PPG Industries v. Guardian Industries, 156 F.3d at 1355, 48 USPQ2d at 1355. If applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional

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steps or components would materially change the characteristics of applicant's invention. See In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman.

Claims 1-5, 7-12, 15-19, 23-26, 29-33, and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Connors (Chicago Sun-Times, July 6, 1991).

Connors discloses a method of treating dry facial skin by applying thereon a composition comprising 1 ounce of glycerin, 2 ounces of witch hazel, and 2 ounces of rosewater. See Beauty Briefs. See instant claims 2-5, 9-11, 16-19, 23-26, 30-33, 37-40.

Although Connors does not specifically teach the recited process of instant claims 1, 8, 15, 22, 29, and 36, the claimed inventions are anticipated by the reference because the usual practice of the prior art method necessarily performs the claimed process. It is well settled in patent law that the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See In re Best. Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. See In re King. Since the Connors composition meets all the limitation of the composition used in the present invention, the administration of the

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prior art composition to the facial skin as disclosed would necessarily result in the treatment of the skin as claimed by applicants.

While the absorption time of glycerin as recited in the present claims 2, 9, 16, 23, 30, and 37 are not taught in the reference, since the claimed and prior art products are identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. See In re Best. It is also well settled in patent law that, when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. See In re Spada. Thus, the absorption time as claimed is viewed an inherent property of the composition comprising the polyols since the applicants' compositions read on the prior art glycerin composition.

It is also noted that the claims require that the compositions consist essentially of water and the organic solvent(s), whereas the prior art compositions comprise witch hazel. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See PPG Industries v. Guardian Industries. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See In re De Lajarte.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 13, 20, 27, 34, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto as applied to claims 1-3, 5, 7-10, 12, 14-17, 19, 21-24, 26, 28-31, 33, 35-38, 40, and 42 as above, and further in view of Charu (US 5914334).

While Okamoto teaches polyethylene glycol (PEG) as a hydrophilic humectant generally and specifically illustrates a cream composition comprising PEG 2000, the reference does not specifically mention lower molecular PEG as required by the instant claims.

Charu teaches that PEG 400 is used as a solvent to formulate a stable gel formulation for topical treatment of skin conditions. See p. 4, lines 50 – 67. The reference teaches that the glycol is a liquid which is completely miscible with water, and that the composition can be compounded easily. Furthermore, the reference teaches that PEG 400 is chemically stable and does not support microbial growth, and that the compositions prepared with the glycol does not dry on skin readily after application.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made to modify the composition of Okamoto by incorporating PEG 400 as motivated by Charu because 1) Okamoto teaches polyethylene glycol as a humectant useful for a topical formulation; and 2) Charu teaches that PEG 400 is a chemically stable solvent, and does not support microbial growth, and easily forms a

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composition which does not dry readily. The skilled artisan would have had a reasonable expectation of successfully producing a stable aqueous composition which moisturizes and improves rough skin and wrinkles, and further provides the benefits of the PEG 400 which Charu teaches.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6616923.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods for treating facial

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skin by administering compositions consisting essentially of water and liquid organic substance having the overlapping limitations.

Conclusion

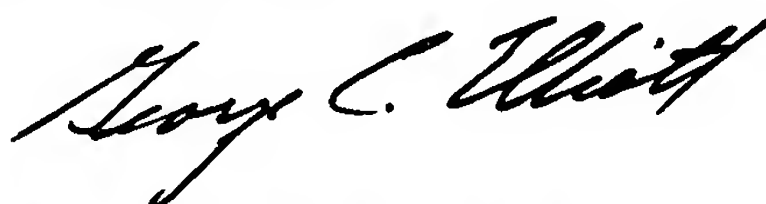
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 7:00AM until 4:30 PM.

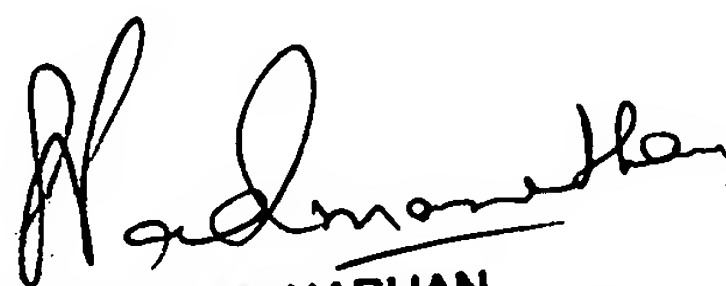
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
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